

**PAIN RELEASE- menthol liquid**  
**Saje Natural Business Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Pain Release Topical Analgesic Mist (100 ml)**

***DRUG FACTS***

***Active ingredient***

Menthol 0.25%

***Purpose*** Topical Analgesic

***Uses*** For the temporary relief of pain and itching associated with minor cuts, scrapes, or insect bites.

***Warnings***

**For external use only.**

**Do not use**

- if epileptic
- with high blood pressure

**When using this product,**

avoid contact with the eyes

**Stop use and ask a doctor if**

condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

**If pregnant or breast-feeding,**

do not use this product.

**Keep out of reach of children.**

If product is swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

- Adults and children 12 years of age and older: Apply to affected area not more than 3 to 4 times daily.
- Not recommended for children under 12 years of age.

### ***Inactive ingredients***

Anthemis nobilis flower oil, eucalyptus oil, lavender oil, melaleuca leucadendron cajaput oil, origanum majorana leaf oil, peppermint oil, rosmarinus officinalis (rosemary) leaf oil, and water.

### ***Questions?***

1-877-275-7253

Distributed by: **SAJE NATURAL WELLNESS** 22 East 5th Ave Vancouver, BC Canada V5T 1G8 | [saje.com](http://saje.com) | **1-877-275-7253** | Made by our friends in Canada

**DO NOT USE IF SECURITY SEAL AROUND CAP AND BOTTLE'S NECK IS BROKEN OR MISSING**

SKU 376701

We support recycling. Please recycle where possible.

### **Pain Release Topical Analgesic Mist (100 ml)**

Saje® Natural Wellness

#### **Pain Release**

#### **Topical Analgesic Mist**

3.4 fl. oz. | 100 ml



IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USING. KEEP THIS PACKAGE FOR FULL INFORMATION.

#### Drug Facts

Active ingredient	Purpose
Menthol 0.25%.....	Topical analgesic

**Uses** For the temporary relief of pain and itching associated with minor cuts, scrapes or insect bites.

#### Warnings

For external use only.

Do not use • if epileptic • with high blood pressure

When using this product, avoid contact with the eyes.

Stop use and ask a doctor if condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant or breast-feeding, do not use this product.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions** • Adults and children 12 years of age and older: Apply to affected area not more than 3 to 4 times daily • Children under 12 years of age: Consult a doctor

**Inactive ingredients** Anthemis nobilis flower oil, eucalyptus oil, lactobacillus ferment (from L. acidophilus), lavender oil, melaleuca leucadendron cajaput oil, origanum majorana leaf oil, peppermint oil, rosmarinus officinalis (rosemary) leaf oil, water.

DO NOT USE IF SECURITY SEAL AROUND CAP AND BOTTLE'S NECK IS BROKEN OR MISSING.

**Saje®**  
NATURAL WELLNESS



**Pain Release**  
topical analgesic mist



LOT NUMBER  
PLACEMENT



SKU 376701

PRICE STICKER  
PLACEMENT

3.4 fl oz

100 ml

Distributed by:

**SAJE NATURAL WELLNESS**  
22 EAST 5TH AVE VANCOUVER, BC CANADA  
V5T 1G8 | SAJE.COM | @SAJEWELLNESS  
MADE BY OUR FRIENDS IN CANADA

QUESTIONS? CALL 1-877-275-7253

100% MADE FROM RECYCLED PAPER.  
please recycle where possible

# PAIN RELEASE

menthol liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70983-005
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.23 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
CAJUPUT OIL (UNII: J3TO6BUQ37)	
SWEET MARJORAM OIL (UNII: ICH7BE016E)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
WATER (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	white (clear)	<b>Score</b>	
<b>Shape</b>	FREEFORM (liquid)	<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70983-005-08	1 in 1 BOX	10/16/2016	
1		100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/16/2016	

**Labeler** - Saje Natural Business Inc. (203413380)

## Establishment

Name	Address	ID/FEI	Business Operations
Natures Formulae Health Products Ltd.		241385587	manufacture(70983-005)

Revised: 11/2021

Saje Natural Business Inc.